



Royal Pharmaceutical Society of Great Britain

Helping pharmacists achieve excellence

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Dear Caroline,

Proposals for amendments to Waste Management Licensing Exemptions relating to Hazardous Waste

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, which is expected to become statutory under anticipated legislation.

The primary objectives of the Society are to lead, regulate, develop and represent the profession of pharmacy.

The Society leads and supports the development of the profession within the context of the public benefit. This includes the advancement of science, practice, education and knowledge in pharmacy. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

The Society has responsibility for a wide range of functions that combine to assure competence and fitness to practise. These include controlled entry into the profession, education, registration, setting and enforcing professional standards, promoting good practice, providing support for improvement, dealing with poor performance, dealing with misconduct and removal from the register."

There are a number of comments to make in relation to the revision of the Waste Management Licensing exemptions. Of particular interest to the Society are the proposed changes to Regulation 39.

- We support the amendment to require storage of waste medicines in secure containers at the pharmacy and believe that this additional requirement will have little impact on pharmacy.
- Whilst we understand the need for compliance with the various Waste Directives, the exclusion of hazardous waste in Regulation 39 (1) is an example of a regulation that

will potentially have unintended consequences. In view of the fact that there is no longer an exemption from Waste Management Licensing, this would mean that pharmacies would have to apply for a licence to store these products, which have been returned from households and individuals. The exclusion of hazardous waste (the definition of which has been suggested is wider than just cytotoxics and cytostatics) will have the effect of ensuring that pharmacists will no longer accept back from individuals and households hazardous waste products. This means that arrangements will have to be made for patients' own hazardous waste medicines to be disposed of other than via a pharmacy. These medicines are by their very nature a possible risk to the public if not disposed of properly and promptly.

- There is also another unintended problem with the proposed amendment. Medicines returned by patients are not sorted or segregated and invariably contain a mixture of items, some of which have had labels removed and are not easily identifiable. It is neither practical, possible nor economical for a pharmacist to sort through medicines at the point of return and only accept those that are non hazardous. This means that under the current regime, the pharmacist must treat the whole bag as if it were hazardous, and consign as hazardous waste. If the new proposals are adopted, then pharmacists could no longer accept back ANY waste medicines – for fear that they may contain a hazardous medicine. The consequence is that unless suitable alternative arrangements are made, unwanted medicines, including hazardous waste will be put into domestic refuse and end up on land fill.
- We are not clear about the interpretation in s39(1) in relation to 'pending recovery', we would want to ensure that waste medicines returned to pharmacies and subsequently disposed of via licensed waste disposal contractors fell within the remit of this section.
- It is clear that in view of the options and the likely effect of the proposed exclusion of hazardous waste under these new proposals that there will be a greater risk to the environment if patients are no longer able to take medicines to pharmacies for disposal. The other potential risks of a failure to allow a proper system in place for disposal of medicines is the risk of overdose, diversion and harm to the environment.
- The Society would, in fact, welcome further amendments to Regulation 39 to ensure that the unnecessarily restrictive nature of the Regulation does not increase the challenge of ensuring that patients' own waste medicines are adequately disposed of.
- We believe that there is justification for the broader exemption under Regulations 39(2) applying to medical practices is no longer justifiable.

- The Society would like to see the extension of the exemptions in Regulation 39 to include:
 - 1) (a) the storage in secure containers at a pharmacy of 'pharmaceutical products' (to include 'sharps') pending disposal that have been returned by an individual or household provided that:
 - 1(b) the total quantity of such returned waste pharmaceutical products at the pharmacy does not exceed 5 cubic metres at any time; and
 - 1(c) any waste pharmaceutical products so returned to the pharmacy are not stored there for longer than six months.

The Environment Agency has already provided advice on the website to indicate that the secure storage of waste sharps at a Pharmacy returned from households and by individuals is a low risk activity and they would not expect pharmacies to obtain a licence for this activity.

- 2) The destruction of a controlled drug by a health care professional which has been returned by an individual or a household.

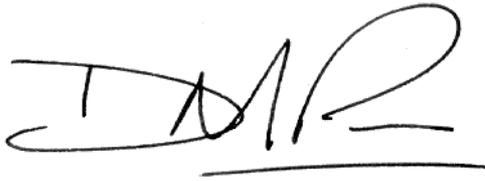
The Environment Agency has already provided advice on the website to indicate that this waste treatment activity is a low risk activity and that they would not expect pharmacies to obtain a licence for this activity. The Society would want to see this exemption set out in the Regulations

- 3) The carriage of unwanted pharmaceutical products from an individual or household by a pharmacy, for the purpose of storage or destruction as specified in paragraphs (1) or (2) above.

This would allow pharmacists who are making domiciliary visits to remove waste medicines from individual patients or households in order to transport them to a pharmacy for proper and safe destruction.

We would be happy to expand on any of these points if it would help or to comment on any further drafts.

With best wishes,

A handwritten signature in black ink, appearing to read 'D. Pruce', with a horizontal line underneath the letters.

David Pruce
Director of Practice & Quality Improvement